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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/882,431 | 06/25/1997 | ROBERT G. ULRICH | 003/037/SAP | 4135 |

7590 06/28/2002

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[REDACTED] EXAMINER

ALLEN, MARIANNE P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 32 |

DATE MAILED: 06/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 08/882,431 | ULRICH ET AL. |
| | Examiner Marianne Allen | Art Unit 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 April 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 4-6 and 12-14 is/are allowed.

6) Claim(s) 1, 18, 43, 44, 53, 62 and 110 is/are rejected.

7) Claim(s) 29-31, 37-39, 47-49, 56-58 and 65-67 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,12-14,18,21-23,29-31,37-39,43,44,47-49,53,56-58,62,65-67 and 110.

DETAILED ACTION

Continued Prosecution Application

The request filed on 4/10/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/882,431 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 4/10/02 has been entered.

Claim Rejections - 35 USC § 112

Claims 1, 18, 43-44, 53, 62, and 110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite "at least two amino acids" and several ranges of amino acids. There does not appear to be basis for altering amino acids in the range of amino acids 18-28, 55-65, 62-72, 86-96, 89-99, and 205-215. None of these specific ranges are disclosed at any of the pages of the specification referred to by applicant and there is no explanation as to how these ranges were derived. If applicant has constructed these ranges as being within five amino acids of a particular amino acid such as 23, for example, the disclosure does not support this concept. The concept of within five amino acids was disclosed with respect to particularly named amino acid positions, not any amino acid position disclosed. Clarification is requested.

In particular with respect to new claim 110, not every amino acid in the recited ranges has been mutated and a particular construct (pETB2360210) does not provide basis for a generic

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claim. Likewise, with respect to SEQ ID NOS: 5 and 6. It is unclear what applicant believes the basis for this claim to be.

Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing as amended in reciting a vector and an isolated fragment. This does not make clear that the DNA is contained within the vector. See claim 18 as amended.

Conclusion

Claims 4-6 and 12-14 are allowable.

Claims 29-31, 37-39, 47-49, 56-58, and 65-67 are objected to as depending upon rejected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
June 18, 2002